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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,030	12/12/2003	Vahid C. Saadat	USGINZ02513	3503
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LEVINE BAGADE HAN LLP 2483 EAST BAYSHORE ROAD, SUITE 100 PALO ALTO, CA 94303				
			EXAMINER	
			LANG, AMY T	
			ART UNIT	PAPER NUMBER
			3731	
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			11/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/735,030

Applicant(s)

SAADAT ET AL.

Examiner

Amy T. Lang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-30, 32-35 and 39-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-30, 32-35 and 39-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. **Claim 30** is objected to because of the following informalities: Claim 30 recites "at least one section of the overtube comprises is steerable," which is incorrect in context. Applicant is advised to change the language to read, "comprises a steerable section" or "is steerable." Appropriate correction is required.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. **Claims 26 and 41-44** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10, 12, 21-28, and 43 of copending Application No. 10/734,562. Although the conflicting claims are

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not identical, they are not patentably distinct from each other because US '562 claims an apparatus comprising an overtube having a flexible and a rigid state, a mechanism that operates to transition the overtube between the two states, and an end effector to form a tissue fold. This apparatus would inherently be capable of engaging mucosa, muscularis, or serosa.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. **Claims 26-30, 32-35, and 39-44** are rejected under 35 U.S.C. 103(a) as being unpatentable over Laufer (US 2004/0194790 A1) in view of Jaffe (US 2002/0161281 A1).

With regard to **claim 26**, Laufer discloses an apparatus for performing a medical procedure within a hollow body organ (see entire document). As shown in Figure 1, the apparatus comprises a distal anchor delivery system comprising distal end effector (718) and shaft (710) ([0079]; [0080]). The distal end effector comprises first and second jaw members (720, 722), which secure and anchor a tissue fold ([0080]; Figures 9F and 10). Shaft (710) comprises a bending section that enables the entire shaft to be generally aligned with the longitudinal axis (Figure 3A) to a second position in which the bending section is generally transverse to the longitudinal axis (Figure 1; [0080]). Therefore, shaft (710) clearly overlaps the instant claimed flexible delivery catheter.

Laufer also discloses another tissue engaging component, coil (740), disposed on catheter (742) ([0083]). As shown in Figure 9E, coil (740) contacts the tissue at a first tissue contact point ([095]). Therefore, catheter (742) clearly overlaps the instantly claimed first catheter.

Although the apparatus of Laufer is an endoscope device designed to access the stomach cavity through a tortuous path ([0079]), Laufer does not specifically disclose an overtube surrounding the endoscope shaft (710).

Jaffe discloses an overtube, guide tube (14), designed to facilitate insertion of an endoscope through a tortuous pathway ([0002]). The guide tube is slideably disposed over the catheter and comprises a flexible and rigid state (Figure 1; [0028]; [0037]; [0038]). As shown in Figure 3, tensioning elements (30) transition the overtube between the flexible and rigid states ([0041]). Therefore, tensioning elements (30)

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clearly overlap the instantly claimed mechanism. It the examiner's position that the tensioning elements are configured to be manipulated from outside a patient's body.

Since the overtube of Jaffe advantageously facilitates insertion of an endoscope through an internal passageway, it would have been obvious to one of ordinary skill at the time of the invention for Laufer to utilize the overtube of Jaffe.

With regard to **claims 27-29**, Jaffe teaches wherein tensioning elements (30) are placed circumferentially about the overtube to control the transition from a flexible to rigid state or vice versa. The tensioning elements may be manipulated individually, so that only one portion of the overtube is transitioned ([0041]). For instance, as shown in Figure 3 of Jaffe, when only tensioning element 30B is manipulated, only that side of the overtube would transition from a flexible to a rigid state or vice versa. The side of the overtube that tensioning element 30D runs would not transition, so that only one section of the overtube remains in a flexible or rigid state while another section is manipulated and transitioned to the opposite state.

With regard to **claim 30**, Jaffe further discloses tip (26), which is steerable (Figure 1).

With regard to **claim 32**, Laufer further discloses a second tissue contact point formed by distal end effector (718) (Figure 9E).

With regard to **claim 33**, Laufer teaches wherein once coil (740) is inserted in the tissue at the first tissue contact point as shown in Figure 9D, a control knob pulls coil proximally ([0095]). This then also pulls the tissue at the first tissue contact point

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proximally and a tissue fold is formed ([0095]; Figure 9E). Therefore, the control knob clearly overlaps the instantly claimed tissue approximation device.

With regard to **claims 34 and 35**, the anchor delivery system of Laufer comprises two tissue-engaging members (720 and 722) that form a second and third tissue contact point (Figure 4A). As shown in Figure 9D, the location of the third tissue contact point is initially in line with the location of the first tissue contact point. Once coil (740) proximally moves the first tissue contact point, a tissue fold is created so that the second and third tissue contact points are located on opposite sides of the fold (Figure 9E). The control knob causes the first tissue contact point to move linearly with respect to the third and second tissue contact points.

With regard to **claims 39 and 40**, Laufer further discloses the distal end effector comprising needles (818a, 818b) through which an anchor is delivered ([0092]; Figure 6B).

With regard to **claims 41-44**, the apparatus disclosed by Laufer in view of Jaffe is configured to engage mucosa, muscularis, or serosa.

Response to Arguments

7. Applicant's arguments, filed 5/29/2007, with respect to the 35 USC 112 rejection, the 35 USC 102 rejection of Silverstein (US 5,052,778), and the Double Patenting rejections of US 6,960,163 and US 6,942,613 have been fully considered and are persuasive. The rejections have been withdrawn.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy Lang whose telephone number is (571) 272-9057. The examiner can normally be reached on Monday - Friday, 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

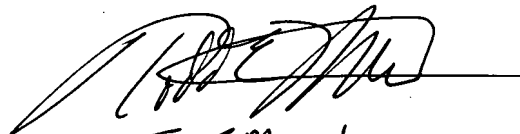
For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

11/08/2007
Amy T. Lang

ATL

A handwritten signature in black ink, appearing to read "Todd E. Monahan".

Todd E. Monahan

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